APPENDIX A

PATENT ACT, 35 U.S.C.

§112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. A claim may be written in independent or dependent form, and if in dependent form, it shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. (Amended July 24, 1965, Public Law 89-83, sec. 9, 79 Stat. 261.)

FEDERAL RULES OF CIVIL PROCEDURE

Rule 52 (a)

In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions

the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. The findings of a master, to the extent that the court adopts them, shall be considered as the findings of the court. If an opinion or memorandum of decision is filed, it will be sufficient if the findings of fact and conclusions of law appear therein. Findings of fact and conclusions of law are unnecessary on decisions of motions under Rules 12 or 56 or any other motion except as provided in Rule 41(b).

APPENDIX B

IN THE

UNITED STATES COURT OF APPEALS

FOR THE SEVENTH CIRCUIT

No. 16421 SEPTEMBER TERM 1967—APRIL SESSION 1968

BAXTER LABORATORIES, INC.,
Plaintiff-Appellant,
v.
CORN PRODUCTS COMPANY,
Defendant-Appellee.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

May 1, 1968

Before HASTINGS, *Chief Judge,* DUFFY, *Senior Circuit Judge, and* CUMMINGS, *Circuit Judge.*

DUFFY, *Senior Circuit Judge.* Plaintiff is the owner of Wallerstein U.S. Patent No. 2,531,999, issued November 28, 1950, based on an application filed October 13, 1947. The term of this patent expired on November 28, 1967. The patent is on a method of converting ordinary plant starch to crystalline dextrose. The process is generally characterized as an "enzyme hydrolysis" of starch. Plaintiff sued defendant for infringing this patent, and defendant filed a counter-claim praying for a declaratory judgment that patent No. 2,531,999 is invalid.

The trial court found the patent invalid for failure to satisfy the requirements of 35 U.S.C. § 112. The Court stated: "The specification of the Wallerstein patent is

not written in 'full, clear, concise and exact terms' " as required by the statute. However, on the assumption that the Wallerstein patent is valid, the Court found ". . . defendant's process does not infringe the process claimed by the Wallerstein patent. It does not come within the claims of the Wallerstein patent and does not operate in the same manner. It obtains a different result through different means."

Plaintiff is engaged in the manufacture and sale of pharmaceutical supplies and continues the business of the Wallerstein Company in the manufacture and sale of enzyme preparations. Defendant Corn Products Company is a manufacturer of products derived from corn including the manufacture of crystalline dextrose which it sells the trade-name "Cerelose."

Dextrose is a chemical substance of the class of carbonates. It has a sweet taste and has a high nutritive value. Dextrose is sometimes called "corn sugar." Crystalline dextrose is manufactured from corn starch or some other plant starch by a crystallized chemical change known as hydrolysis. It is a relatively pure form of dextrose. It is to this particular product that the Wallerstein patent relates.

The hydrolysis of starch to dextrose using acid as a catalyst was conceived as early as 1811 by the Russian scientist Kirchoff. He produced a dextrose syrup which could be used as a liquid syrup or reduced to dry form as crystals or as a solid slab.

The possibility of using an enzyme preparation to hydrolyze starch to dextrose was known as early as 1927. The difficulty encountered was to effect such a hydrolysis of starch on an economical commercial basis.

In the process of hydrolysis, starch usually is suspended in a relatively large amount of water. This starch suspension is frequently referred to as "substrate." Since the starch chains molecule is relatively stable, the process of hydrolysis does not readily occur. A catalyst is required to initiate and assist the reaction. An acid or an enzyme

may be added to the substrate. The reaction then proceeds through the initial thinning of the starch to the final formation of the dextrose molecules. The resulting "hydrolyzate" is a liquid solution which contains small amounts of reversion products and the residual acid or enzyme.

For commercial purposes, the dextrose is recovered from the hydrolyzate in one of three forms. It can be an ingredient of syrup or solidified into so-called "slab sugar", or the crystals of dextrose may be recovered apart from the other substances.

The enzymes mentioned in this case are derived from fungi (molds). They excrete through their cell walls enzymes of various digestive abilities or activities. A large number of enzymes of "activities" are produced by a culturing of a single kind of mold such as Aspergillus oryzae or Aspergillus niger. Among these activities is an amylase, which hydrolyses starch to dextrose.

Modern science has not been able to chemically define enzymes.[1] They are usually described by what they do, not by what they are.

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[1] Definitions of "Enzyme", "Enzyme Preparation having Starch-Glucogenase Activity" and "Transglucosidase" were stipulated as follows:

"Enzyme: Specific, cell-independent catalysts of biological origin, which are proteinaceous and can be destroyed by heating."

"Enzyme Preparation having Starch-Glucogenase Activity: Any enzyme-containing substance which gives a positive value when subjected to the procedure and calculations described in U.S. 2,531,999, column 3, lines 14 to 51."

"Transglucosidase: An enzyme which produces non-fermentable sugars, e.g., isomaltose and panose, from some starch hydrolysis products."

Leo Wallerstein and his brother founded a brewing consulting laboratory shortly after 1900. Within a few years, they discovered an enzyme which prevented bottled beer from turning cloudy. They founded the Wallerstein Company to market the new product.

After the coming of prohibition, they developed enzymes useful in the textile, leather, baking and other industries. Their company merged with Baxter Laboratories in 1958.

Leo Wallerstein became interested in the use of enzymes to make crystalline dextrose. In the 1940's, he began experiments which led to the invention of the patent in suit.

The fundamental of starch conversion was well known. The deficiencies of acid hydrolysis in producing limited yields of dextrose with relatively high concentration of taste and color imparting reversion products was also recognized.

The patent in suit discloses and claims as invention the basic steps necessary to the successful enzyme hydrolysis of starch to produce a dextrose hydrolyzate of such character that discrete crystals of dextrose may be readily obtained.

It is apparent that Wallerstein knew that the formation of excessive reversion products during the reaction prevented the production of a hydrolyzate suitable for making crystalline dextrose.

In order to increase the yield of dextrose and to facilitate crystallizing, Wallerstein departed from the teachings of prior workers in this field. The patent teaches that no preliminary treatment whatsoever is required prior to adding the enzyme, although for economic reasons some preconversion or acid thinning is desirable. Wallerstein explains that it should be kept to a minimum and that with lesser treatment there will be higher yields of dextrose.

Prior enzyme researchers such as Dale and Langlois had urged preliminary thinning to a dextrose equivalent

(DE) of between 40% and 60%. Wallerstein prefers to keep it below a DE of 30%, and gives examples of lower DE thinning and, in one instance, of none at all.

The patent further teaches that an enzyme of specified minimum potency should be used. Such potency is termed in the patent as "starch-glucogenase" activity.

The patentee defines the potency of the enzyme in terms of its initial reaction velocity "k" and sets forth a formula and analytical procedures for its determination. The patent states the enzyme should have a starch-glucogenase "k" value of "at least 1.0."

The patent in suit was called to the attention of the defendants by its firm of consulting engineers within a month after it had issued. Defendant's Research Department commented that the new process ". . . should be thoroughly investigated before any conclusion can be drawn regarding the economic potentialities of the process."

On June 19, 1954, defendant's Research Department wrote: "A patent recently issued to Wallerstein, U.S. Patent 2,531,999 covering . . . a process which I have always felt would some day be of industrial importance, particularly to our company. The process is limited somewhat . . . by the cost of available enzymes and the unavailability in industrial quantities of most suitable enzymes. . . ."

The commentary pointed out that Aspergillus oryzae is a costly source of the enzymes, and suggested the use of other fungal sources which had been discovered since Wallerstein's invention.

Later, defendant began limiting the preliminary thinning of the starch so as to preclude formation of substantial reversion products prior to the enzyme hydrolysis. The use of "low DE substrates" brought about substantial improvements in the yield of dextrose. As the extent of such pre-treatment was lessened, the extent of final conversion to dextrose was increased. Furthermore, defendant began to purify its enzymes to at least the minimum

potency described in the patent. Enzymes from various fungal sources were used. The more economical Aspergillus niger strains were preferred.

Defendants argue that the alleged invention is invalid because it is obvious in view of the prior art. On the other hand, defendant also argues that the patent is so vague that it violates 35 U.S.C. § 112 and also, that it is so vague as to render it meaningless to one skilled in the art. We disagree. We hold that the patent is not invalid for either reason.

When the Wallerstein patent was issued, defendant's engineers and scientists read it and understood it. They experimented and tried the process and it worked. Answers to interrogatories indicate that defendants tested the procedure as early as 1954.

It is true that defendant's scientists discovered a more economical method to purify the niger enzyme by the absorption of transglucosidase on bentonite clay. However, the enzyme is as described in Wallerstein.

Defendants strongly urge that the discovery of the role of transglucosidase was theirs. However, it appears from defendant's own reports that credit for the discovery of transglucosidase in these fungal sources should go to Pazur, French and others, whose data came into public literature in 1950-1952.

The correct statement of the situation would be that while the enzyme is as described by Wallerstein, the source and the method of procuring it has been improved by defendant and others. As plaintiff amply describes it "Wallerstein laid the road. The defendant drove over it."

Wallerstein's own laboratory experiments proved the success of his process. By use of enzymes as a catalyst, he obtained higher yields of crystalline dextrose. The production of objectionable reversion products was minimized.

Apparently the only reason defendant did not earlier change from acid hydrolysis was the cost involved and the difficulty in obtaining the enzyme needed.

We have considered additional arguments of invalidity made by defendant. Nevertheless, we hold that the claims of the patent in suit here in issue are valid.

As to infringement, defendant refers to the patent in suit as a paper patent which should be narrowly and strictly construed. However, failure by a company not in the business of converting starch or producing crystalline dextrose, to spend large sums for equipment and possibly new buildings, should not be the basis for describing the patent as a paper patent. See *Coltman* v. *Colgate-Palmolive Peet Co.*, 104 F.2d 508, 511 (7 Cir., 1939); *Aerosol Research Co.* v. *Scovill Manufacturing Company*, 334 F.2d 751, 756 (7 Cir., 1964); *Briggs et al.* v. *M. & J. Diesel Locomotive Filter Corp. et al.*, 342 F.2d 573, 577 (7 Cir., 1965).

It is erroneous to say, as does the District Court's decision, that defendant's process does not come within the claims. In our view, defendant's process reads squarely on the process described in the patent. We think it was also incorrect to say that defendant gets a different result through different means. We think defendant obtains the result which Wallerstein described.

The District Court's opinion states: "Since the Wallerstein patent claims a process for the production of crystalline dextrose in a better manner than the acid conversion then employed, and mentions nothing about the removal of transglucosidase from the enzyme employed, the defendant's process is not that of the Wallerstein patent."

It was, apparently, an important consideration in the opinion of the District Court, that the patent did not mention by name the removal of transgulcosidase from the enzyme. It is true that the name transglucosidase was not used, but in 1947, neither Wallerstein nor anyone else knew of the presence of transglucosidase in his enzyme.

The object of the patent in suit was to effect hydrolysis under such conditions that

a) "crystallization is markedly facilitated;"

b) "the production of undesirable by-products of little value minimized"; and

c) "increased yields of dextrose are obtained."

In 1954, defendant, after studying the Wallerstein patent, obtained these objects and did so before it invented an improved enzyme and before removing transglucosidase.

To illustrate the state of the art, defendant's expert, Earl R. Kooi, director of Exploratory Research at Corn Products Co., in 1954, observed as to crystallization "Just why crystallization of dextrose from an enzyme-converted liquor should be so much more rapid than crystallization from an acid-converted liquor is difficult to understand."

We conclude that defendant's commercial process utilizes the *principle* of the Wallerstein invention and achieves the *result intended* by that invention. In its process, defendant limits its pre-treatment of the starch to a low DE and it purifies its enzyme to a "k" of at least 1.0.

We think the proof on the trial demonstrated that in the Wallerstein process it makes no difference whether the dry enzyme is dissolved in one part or thirty parts of water prior to subjecting the starch to it. The results would be no different if the dry enzyme powder was stirred directly into the starch-conversion tanks which hold thousands of gallons of water.

We agree with plaintiff that the "k" value specified by Wallerstein must be determined on the basis of the solid material and not on the basis of solids diluted by water.

Defendant makes a serious charge which is found too often in patent litigation. It argues that the patent in

suit is unenforceable because it was procured by misrepresentation.

As we understand the charge, defendant says Wallerstein's patent solicitor was wrong when he characterized the "k" value of the patent as a "quantitative" expression of the activity of the enzyme. Defendant now says that "k" is a "qualitative" measure of activity and infers that the solicitor misled the patent office.

What is important is that those reading the patent application are fully advised of what "k" means and how it is determined. The District Court found that the "k" method of determining the potency of the enzyme is set out in the patent in "such 'full, clear, concise and exact terms as to enable any person skilled in the art' to likewise measure and determine the potency. . . ." We agree!

We hold that no misrepresentation was made, and that there is nothing in the record to show that the Patent Office Examiner was misled.

Due to the unfortunate length of this opinion, we have not discussed several additional arguments presented by defendant. We have considered the same and are unable to agree with such contentions.

We hold that the claims of the Wallerstein patent in suit here in issue are valid and that such claims are infringed by defendant's process.

The judgment of the District Court is reversed and the cause is remanded for further appropriate proceedings consistent with this opinion.

REVERSED and REMANDED.

APPENDIX C

In The
UNITED STATES COURT OF APPEALS
For The Seventh Circuit
Chicago, Illinois 60604
Friday, June 7, 1968
Before
Hon. F. Ryan Duffy, Senior Circuit Judge
Hon. John S. Hastings, Circuit Judge
Hon. Walter J. Cummings, Circuit Judge

No. 16421

Baxter Laboratories, Inc., *Plaintiff-Appellant,* v. Corn Products Company, *Defendant-Appellee.*	Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.

It is ordered by the Court that the petition for rehearing of this cause be, and the same is hereby, Denied.

APPENDIX D

IN THE UNITED STATES DISTRICT COURT

• • Caption No.—62 C 1757 • •

MEMORANDUM OPINION AND ORDER

Baxter Laboratories, the plaintiff in this case, is a Delaware corporation having its principal place of business in Morton Grove, Illinois. Their complaint accuses the defendant of infringing United States Letters Patent No. 2,531,999, issued on November 28, 1950, entitled "Manufacture of Crystalline Dextrose." The defendant is Corn Products Company, a New York corporation with a regular and established place of business in Summit, Illinois, within this District wherein it allegedly committed acts of infringement. The defendant answered the complaint and filed a counter-claim praying for a declaratory judgment that the patent in suit is invalid. This Court has valid jurisdiction over this controversy based on 28 U.S.C. §1338(a).

The plaintiff is the successor in business to the Wallerstein Company, formerly a corporation of New York, and by merger is the owner of the patent in suit. Rights to this patent were originally assigned by the inventor, Leo Wallerstein, to the Wallerstein Company. The plaintiff is engaged in the manufacture and sale of pharmaceutical supplies and continues the business of the Wallerstein Company in the manufacture and sale of enzyme preparations.

Crystalline dextrose, the subject of the patent in this controversy, is an essential ingredient in the blood of humans and animals, and its oxidation in the body serves

as the source of heat and energy necessary to human existence. It is manufactured from corn starch, or some other starch, by a cataylzed chemical change known as hydrolysis. This chemical change results from breaking up the molecule of starch into smaller pieces to which a molecule of water is attached, thereby producing a molecule of dextrose from each piece.

Neither the plaintiff, Baxter Laboratories, nor its predecessor, Wallerstein Company, is or was ever engaged in the manufacture or sale of crystalline dextrose as a commercial product. Wallerstein Company, during the period from approximately 1945 to 1955, investigated the possibility of developing the manufacture of crystalline dextrose to a commercial state and determined that the enzymatic conversion process would be quite expensive. This investigation culminated in commercial production. Wallerstein Company never made any crystalline dextrose for sale and is not now and never has been engaged in the commercial manufacture of crystaline dextrose under the patent in suit. The several owners of the patent in suit have never commercialized it. No license has ever been granted and no royalties have ever been paid to the owners of the patent. The patent is therefore a "paper patent" and is to be strictly construed. *Standard Oil Co.* v. *Globe Oil & Refining Co.*, 82 F.2d 488 (7th Cir. 1939).

The defendant, Corn Products Company, is a manufacturer of products derived from corn, including the manufacture of crystalline dextrose, which it has sold under the trade name of "Cerelose".

The hydrolysis of starch to dextrose using acid as a catalyst was conceived as early as 1811 by a Russian scientist, Kirchoff. He produced a dextrose syrup which could be used either as a liquid syrup, or when reduced to dry

form, as crystals or as a solid slab. However, the defendant pioneered the commercial production of crystalline dextrose. At first, it was produced on a small scale for medicinal purposes, since the problem of crystallizing dextrose on a commercial scale was extremely complex. But the defendant eventually managed to go into profitable commercial production of crystalline dextrose using acid as a catalyst.

Starch can also be converted to dextrose through a process of hydrolyzing the starch by using an enzyme preparation following preliminary liquefaction of the starch by either acid or enzyme hydrolysis. After subsequent filtration and concentration, syrups of various densities and crystallized glucose can be obtained.

The possibility of using an enzyme preparation to hydrolyze starch to dextrose was known and published as early as 1927, but until relatively recently no one has been able to effect the hydrolysis of starch on an economic commercial basis using an enzyme catalyst. In about 1960, the defendant began to change its starch-to-dextrose conversion step from an acid catalyst to an enzyme catalyst, and has operated its plants, both in the United States and in foreign countries, with an enzyme preparation as the hydrolyzing agent or catalyst since that time.

The first issue to be resolved is the accusation of the complaint that the defendant is infringing plaintiff's patent. For the purposes of this determination, I will assume the patent to be valid.

In order to determine whether there was any infringement of the plaintiff's patent rights by the defendant's production of crystalline dextrose, the Court must define the scope of the plaintiff's patent. These are the boundaries of invention protected by the patent. The Wal-

lerstein patent is entitled "Manufacture of Crystalline Dextrose" and relates to a method whereby ordinary plant starch, such as is commonly derived from corn or potatoes, may be commercially converted, or hydrolyzed to form relatively pure dextrose for use in a variety of industrial and pharmaceutical applications. The Wallerstein patent states (col. 1, lines 25-30):

> It is the object of this invention to effect the hydrolysis of starch under such conditions that crystallization is markedly facilitated, the production of undesirable by-products of litle value minimized, and increased yields of dextrose are obtained.

The Wallerstein patent allegedly discloses that the starch is to be pre-thinned by either acid or an enzyme, or it can be used directly in the enzyme conversion step. The starch or "conversion products thereof" (i.e. thinned or partially dextrinized starch) are then subjected to the action of a microbiological enzyme preparation having a "k" value of at least 1 to convert a substantial proportion of the starch to dextrose. The product of such conversion is then held at crystallizing temperature until discrete crystals are formed, and the crystals are separated from the mother liquor.

The "k" value is meant to represent the initial reaction velocity of the formation of dextrose by the enzyme. The Wallerstein patent sets forth conditions for its determination by a formula long used in enzymology. The "k" value is an indication of the potency per unit of the enzyme.

The Wallerstein application as filed, Serial No. 779,635, October 13, 1947, contained nine claims, all directed to the concept of hydrolysis of starch to dextrose by the action of an enzyme preparation and the subsequent crystalli-

zation and separation of the crystals from the mother liquor. These original claims were rejected both on prior art and because they were too broad and indefinite. Following an interview between applicant's attorney and representatives of the Wallerstein Company with the Examiner, amendments were made on or about April 27, 1950, such that all claims included a limitation that the "k" value of starch-glucogenase activity of the enzyme preparation employed was to be at least 1.0. This limitation of the starch-glucogenase activity to a "k" value of at least 1.0 thus became a characteristic feature of the invention.

One of the defendant's arguments in defending against the charge of infringement is that in their process they employ an enzyme preparation with a "k" value less than 1.0.

The defendant argues that the patent calls for use of an "enzyme preparation" with a "k" value greater than one. In their process, the defendant takes a substance with a "k" value far in excess of 1.0 and adds large quantities of water, thereby reducing the "k" value of enzyme and water mixture far below 1.0. The defendant argues that the "enzyme-and-water mixture which the defendant adds to the starch is the "enzyme preparation" to which the patent refers.

It is true that the terms "enzyme preparation" and "enzyme" are not distinguished or defined in the patent. These terms are seemingly used indiscriminately in the Wallerstein patent specification, while the term "enzyme preparation" alone is usesd in the claims. The "k" value determination, as given in Column 3 of the patent, is the determination of the starch-glucogenase activity of an enzyme preparation as stated in Lines 48-51 of the patent.

The specification of the patent does not specifically exclude measurement of the "k" value on the wet product which is added to the starch and which is arguably the "enzyme preparation" which the patent refers to.

However, the patent claims specify a step of "subjecting an aqueous disperson . . . to the *action of* a microbiological enzyme. . ." to produce dextrose. Defendant is not "subjecting" the aqueous dispersion, containing about two-thirds water, "to the action of" the water with which its enzyme preparation is mixed to produce dextrose. Such water is inert and has no action on the aqueous dispersion. Defendant is "subjecting" the aqueous dispersion "to the action" of the dissolved solids of the enzyme preparation to produce dextrose. The solids contain the starch-glucogenase activity which produce the dextrose. The "k" value of the substance to the action of which defendant is "subjecting" its aqueous dispersion to produce dextrose is in the general area of about 20.

The defendant contends that its "enzyme preparation" is the liquid which it adds to the substrate and that since this is sufficiently diluted to bring the "k" value to below 1, it does not infringe. Unfortunately, the patent claims do not purport to define the condition of the enzyme preparation as it is added to the substrate. But, the claims speak of "subjecting" the substrate "to the action" of the enzyme preparation. During the 72 hours or more employed by the defendant for conversion, it is only the action of the dissolved solids acting to produce dextrose to which the substrate is subjected. The evidence shows that, save for possible convenience in adding the enzyme preparation and originally mixing it with the substrate, there is no difference in result achieved by the dilution. The amount of dilution is selected, not for scientific reasons, but commercial necessity, which require that the

enzyme be easilly dispersed throughout the starch substrate.

The defendant also contends that a reason for diluting its enzyme preparation is to "standardize" its preparation in order to have uniformity of operation. However, the evidence showed that the "k" value of the diluted enzyme, or the glucamylase activity, the term which defendant uses in keeping its records, has varied widely and has not been "standardized". For example, in the month of May, 1964, the units of glucamylase activity at the Argo plant varied widely from day to day - from 10.8, 9.4 and 9.0 on the high side down to 1.7, 2.7 and 3.2 on the low side. There was no standardization of these values, and what they were was immaterial to the outcome of the defendant's process. Standardization, as I would expect the term to be used, was achieved by adding 750 "standard pounds" of enzyme to each batch. The defendant cannot be said to have been "stardizing" by putting the desired number of standard pounds of enzyme preparation in a tank and then filling the tank to its capacity with water, regardless of the amount of water required. This is the defendant's procedure and I cannot consider the adding of water "standardization".

Enzyme preparations, particularly those commercially available, are standardized at a specified potency. This enables the user to establish and follow consistent process dosages. Standardization, as the word is commonly employed is achieved by diluting the enzyme preparation to a preselected potency value. Defendant does not employ such standardization. It merely adds water - in known or unknown amount - sufficient to give a "k" value of the diluted mixture of less than 1.0. Defendant "standardizes", in the true sense, by using dosages of the same amount of "standard pounds" each day (one standard pound of dry

enzyme will contain 100,000 G.A. units - a "k" value of about 20).

The enzymatic *action* of the defendant's enzyme preparation would be identical whether the enzyme were added to the substrate as a powder or diluted with water. The substrate is subjected to the same enzyme activity whether the enzymes be added to the substrate dry, or with a little water, but less than enough to reduce the "k" value to 1, or with so much water that the "k" value becomes less than 1. The "k" value that is significant is the "k" value of the solids which, alone, contain the enzymatic activity. Use of the dry powder or the culture filtrate, each of which has a "k" value well in excess of 1, or defendant's use of the powder or culture filtrate diluted with water to give an "as is" "k" value of less than 1, causes the substrate to be subjected to the action of the identical enzyme and produces dextrose in the same manner, by the same means, and with the same results. I cannot therefore agree with the defendant that the "k" value is to be determined from the enzyme-and-water mixture which is added to the starch.

Defendant contends that the words in the claims of the Wallerstein patent "enzyme preparation" would mean to one skilled in the art the enzyme in the form in which it is added to the substrate, and that the claims refer to the "k" value at that time, regardless of the dilution, if any, with water. Two scientists called as witnesses by defendant testified to this meaning, but this testimony was not on the basis of the general meaning of the words in the art, but on the basis of the particular use of the words in the patent claims. Defendant's assistant director of research, familiar with patents as well as chemistry, and himself a patent applicant of at least one application in this field, remarked, after the possibility of dilution of

the enzyme to avoid infringement of the Wallerstein patent was suggested to him:

> I conceive of no scientific or legal basis for distinguishing between wet and dry enzyme preparation. We do not base our yield of dextrose on starch liquor but on starch. Whether the enzyme is prepared in water, extracted with water, or precipitated from water and is subsequently concentrated or diluted with water, can have little significance. It will be generally accepted that the enzyme activity is to be measured on a water-free basis.

One skilled in the art would know that the "k" value specified in the Wallerstein patent claims is the "k" value of the solids, and not the "k" value of solids diluted by addition of inert water. The enzymatic activity of the material is entirely in the solids, and "k", a measure of potency, should be determined on that basis.

The use of the words "enzyme preparation" in the patent claims is a proper, clear use of the words to mean "enzyme or enzymes" in the enzymatic substance. The use of the words "subjecting . . . to the action of a microbiological enzyme preparation" in the patent claims is a proper, clear statement that the substrate is subjected to the action of an enzyme or enzymes having the specified "k" values. While the Wallerstein patent does not expressly state that the "k" of the enzyme is to be measured exclusive of diluents, one skilled in the art would know that adding or taking away water would have no effect upon the activity of the enzyme and that its "k" value should be determined on a dry basis.

If it were true that the issue surrounding the definition of the "k" value was all that the Court need decide in order to determine infringement, judgment would be

entered for the plaintiff. However, defendant also argues that the process that they employ falls outside the claims of the plaintiff's patent since it includes as vital elements the use of inventions made by defendant on which the defendant has its own patents. I find that I am in agreement with this position.

The process patented by Wallerstein was described in the patent (col. 1, lines 30-40) as:

> . . . hydrolysis of starch and its partial conversion products is effected by suitable enzyme action under proper conditions, in which any preliminary breakdown of starch is limited in such a way as to minimize formation of reversion products capable of interfering with the crystallization, and the final hydrolysis with enzymes is conducted in such a way as to obtain a completeness of hydrolysis and a purity of hydrolsate, with respect to dextrose, not possible with known methods.

At this point, it would be helpful to note that a "transglucosidase" enzyme is one which forms products such as panoses and isomaltose from maltose. If one is seeking to form dextrose from starch, the presence of transglucosidase will cause some of the maltose to form products like isomaltose, which are undersirable since they cannot be readily converted into dextrose by a starch-glucogenase enzyme preparation, the presence of this type of enzyme thereby decreases the yield of crystallizable dextrose. While it had been known for a number of years that there were transglucosidase enzymes, not until about 1950 or 1951, after the issue of the Wallerstein patent, was it known that such enzymes might be found in enzyme preparations obtained from the fungal sources Aspergillus niger and Aspergillus oryzae. The specifications of the patent do not mention the words "purity" or "purifica-

tion" in connection with enzyme or enzyme preparation. The possibility of removing the transglucosidase activity from the enzyme preparation used in the suggested process was nowhere mentioned in the Wallerstein patent.

In addition, it is worth noting that results of experiments produced by the defendant at the trial demonstrated that increasing the "k" value by precipitation did not remove transglucosidase nor increase dextrose yields. They also established that removal of transglucosidase did not substantially change the "k" value. It was shown that removal of transglucosisdase from the enzyme preparation resulted in raising the dextrose content of the hydrolyzate beyond the value which could be attained by use of the enzyme preparation from which transglucosidase had not been removed.

It is very relevant at this point to examine in part the history of the development of the defendant's process. In about 1949, the defendant's research laboratory investigated the commercial feasibility of employing enzymatic conversion of starch with commercially available enzyme preparations as a substitute for acid conversion in their process of producing crystalline dextrose. This conversion produced 83% dextrose (dry basis), corresponding to a crystalline dextrose yield of 62%. This new process was not then competitive with acid conversion.

Further research and investigation brought about improvement in enzyme production around 1954 by improvement in nutrient solution which increased enzyme yield (GA units per milliliter) by a factor of about 9 and increased dextrose content to 90% and crystalline yield to 78%. By 1956, the improvement in enzyme production had more than doubled the 1954 figure of GA units per milliliter. The dextrose content dropped slightly to 86% and the crystalline dextrose yield was 69%.

The study of enzyme preparations for starch hydrolysis to dextrose conducted by the research department of Corn Products Company revealed the injurious effects of transglucosidase.

As a result of the defendant's study of transglucosidase in the enzyme preparation derived from Aspergillus niger, a method was discovered for removing the transglucosidase without substantial diminution of the saccharogenic fractions of the enzyme preparation. In 1956, the method of removing transglucosidase from the enzyme preparation was developed and patented (Kooi et al, 3,042,584). This did not increase the GA units per milliliter, but it did increase the dextrose content of the hydrolyzate to about 93%. This discovery was important as an inexpensive way of increasing the dextrose content of the hydrolyzate derived from the treatment of starch by an enzyme preparation in order to convert it to dextrose.

Patent No. 3,042,584, granted July 3, 1962, on Application Serial No. 77,531 filed December 22, 1960, continuation-in-part of Application Serial No. 666,469 filed June 18, 1957, in the names of Kooi, Harjes and Gilkison contains a full explanation of this inventive contribution and its mode of use and its advantages. Without the benefit of this discovery, the defendant's development of a commercial process would not have materialized.

By 1958, the defendant had developed the process of precipitating the enzyme to provide a dry powder concentrate suitable for storage and shipment. In 1960, the defendant discovered and developed mutants of Aspergillus niger (disclosed in Armbruster Patent 3,012,944) having superior yields of GA units per milliliter than previously known microorganisms. The research department of the defendant discovered, isolated, and cultured Asp-

ergillus niger mutant, Armbruster C-14 No. 13,497, from Aspergillus niger CPC M-370, which was isolated from soil sample obtained from Baton Rouge, Louisiana. Patent No. 3,012,944 was granted December 12, 1961, in the name of Frederick C. Armbruster on "Enzyme Preparation". This patent discloses the characteristic features, description and origin of the specific microorganism and its peculiar ability to yield glucamylase in larger amounts than any theretofore known microorganism.

This line of research and development work increased the glucogenase yield in terms of units per milliliter by about 70 times that which was initially available. At the same time, the fermenting capacity which was required for production of a given amount of enzyme dosage was reduced by a corresponding amount.

In 1960, the defendant substituted enzymes for acid as hydrolyzing agent. This would not have resulted in the economic commercial production of crystalline dextrose if the immediately preceding developments had not been made by the defendant.

I am satisfied from the evidence produced at the trial that the process employed by the defendant could not result in the economic commercial production of crystalline dextrose if a purified enzyme were not employed. In other words, if the defendant did not treat the enzyme they employ so as to remove the transglucosidase activity, the results they achieve would not be superior to the acid conversion process which they had employed in the past.

Since the Wallerstein patent claims a process for the production of crystalline dextrose in a better manner than the acid conversion then employed, and mentions nothing about the removal of transglucosidase from the enzyme employed, the defendant's process is not that of the Wallerstein patent.

Therefore, it is my conclusion that the defendant's process does not infringe the process claimed by the Wallerstein patent. It does not come within the claims of the Wellerstein patent and does not operate in the same manner. It obtains a different result through different means.

The defendant's process employs two important inventions which provide: (1) transglucosidase removal by an inexpensive absorption process (Kooi et al, 3,042,584), and (2) a microorganism that produces enzyme at a lower cost and with better glucamylase to transglucosidase ratio (Armbruster 3,012,944). Without at least the first of these inventions, defendant could not have gone into the production of crystalline dextrose by enzyme conversion.

In addition, the defendant's position is that there has been no infringement because the patent is invalid. This is pleaded both as a defense to the charge of infringement and as a counterclaim for a declaratory judgment.

The pertinent statutory section regarding patents, 35 U.S.C. §112, reads in part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The defendant urges that the patent in suit fails to satisfy the requirements set out by this statutory section. It is argued that the evidence shows that the patent fails in numerous ways. Many of these are contradictory to each other and one wonders how the defendant hoped to

persuade the Court of the truth of these proposed self-contradictory findings. Possibly the most glaring example of this is the defendant's proposed findings which suggest on the one hand that the evidence shows that the invention is obvious from the prior art, and on the other hand that the patent is so vague as to render it meaningless to one skilled in the art. Certainly, maintaining both of these results at the same time offends logic. The defendant, nevertheless, suggests that I adopt findings of fact which would support both conclusions. I have found the defendant's proposed findings of fact and conclusions of law rather unhelpful. Nevertheless I am in agreement with defendant's conclusion that the patent in suit is invalid.

The patent specification says, Column 3, Lines 52-70:

> *In general,* to obtain starch hydrolyzates which readily form discrete crystals of dextrose it is desirable to use an enzyme preparation having a starch-glucogenase activity sufficient to effect *substantially complete* hydrolysis of the starch substrate in *not more than* 72 hours when *not more than* 1% of the enzyme preparation, based on the weight of the starch, is employed. Such an enzyme will have a "k" value *of the order of 1.0.* Enzyme preparations having a "k" value as high as 10 or even higher may be employed, the amount of the enzyme preparation used being decreased in proportion to the increasing "k" value. *In general,* the amount of the enzyme preparation used should be *at least about* 1/"k" parts by weight of starch or starch conversion products and *preferably about two to three times* this proportion of enzyme is used. (Emphasis added).

Upon first reading this portion of the patent it is apparent that the specification lacks the specificity which

would seem necessary in order to adequately desccribe an invention. Phrases such as "in general", "at least", "not more than", "on the order of", and "substantially complete" do not lend themselves to a precise scientific description of a process to be patented.

A more specific examination of the patent would serve to point up this criticism more clearly. The above quoted statement from the specifications says that there are three essential factors that control the hydrolysis operation; that they are interrelated to each other; and that the potency of the enzyme preparation to be employed shall be of a value of at least 1.0. The other factors must conform to the "k" which is adopted.

The three crucial factors set out by the specification are: (1) the potency of the enzyme in terms of its "k" value, (2) the amount of enzyme preparation as a per cent of the amount of starch, and (3) the time required to complete the hydrolysis.

Considering these three essential elements in the order provided above, I first find that the *manner* of determining the potency of the enzyme in terms of its "k" value is sufficiently described. In other words, the patent adequately describes how to determine the "k" value of an unknown enzyme preparation. This description, of course, is separate from a description of what amount that "k" value should be to make the process operate successfully. Various workers in the art already had proposed various methods of determining the potency of an enzyme preparation. Since the chemical composition, as well as the physical characteristics, of a pure enzyme were insufficiently known to constitute accurate definitions of specific enzymes, the art had adopted the practical yardstick of how much of a specific starch preparation will be convert-

ed in a given period of time per gram of the enzyme preparation.

The Wallerstein patent specification adopted a complicated method and formula for determining the potency of an enzyme preparation in regard to starch-glucogenase activity. This method assimilated the unimolecular reaction constant "k" from the unimolecular reaction law expressed in the equation:

$$k = 1/t \log 10 \; a/a\text{-}x$$

In the application of the unimolecular reaction constant "k" to potency or starch-glucogenase activity, the unimolecular reaction law, as expressed in the formula, is applied to the first thirty minutes of action upon the starch substrate of the enzyme preparation to be assayed or measured. For convenience of the determination, the various actions and conditions are arranged so that 50% hydrolysis is effected on the substrate in thirty minutes.

I find that this method of determining the potency of the enzyme preparation to be used in the process described by the patent is set out in such "full, clear, concise, and exact terms as to enable any person skilled in the art" to likewise measure and determine the potency of an enzyme to be employed in converting starch to crystalline dextrose.

But, knowledge of how to determine the potency of any given enzyme preparation is not equivalent to knowledge of the potency of the specific enzyme preparation to be employed in the patented process. In this regard, I find the patent specifications wanting.

The patent specifications state that the enzyme preparation to be employed "will have a 'k' value *of the order of* 1.0." I am convinced from the testimony at the trial

that this description of the "k" value of the enzyme preparation is not described so as to provide one skilled in the art "full, clear, concise, and exact" directions as to how to make an enzyme preparation with the potency needed for the successful practice of the process Wallerstein attempted to patent.

To describe the potency *"of the order of* 1.0" is not a sufficient disclosure to warrant a patent monopoly. It provides nothing more than a scant clue as to the potency to be used. No upper or lower limit is given on the "k" value in the process that Wallerstein claimed. The public is left without notice of the process which Wallerstein attempted to patent and has no way of determining whether a process they might choose to employ has avoided the Wallerstein patent or is infringing. Section 112 was designed to "guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their rights." *United Carbon Co.* v. *Binney & Smith Co.*, 317 U.S. 228 (1942). In *Universal Oil Co.* v. *Globe Co.*, 322 U.S. 471, the Supreme Court stated at Page 484:

> As a reward for inventions and to encourage their disclosure, the United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret. But the quid pro quo is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted.

In *Schriber-Schroth Co.* v. *Cleveland Trust Co.*, 305 U.S. 47 (1938), the Supreme Court stated at Page 57:

> The object of the statute is to require patentee to describe his invention so that others may construct and use it after expiration of the patent, and to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.

See also: *Research and Development Corporation of Ill.* v. *Chase,* 88 F.2d 353 (7th Cir. 1937).

The second element is the amount of enzyme in relation to the amount of starch. I find that this element also is not set out in the patent in such a way as to satisfy the statute. The patent reads, Column 3, Lines 65-70:

> In general, the amount of the enzyme preparation used should be at least 1/"k" parts by weight for each 100 parts by weight of starch or starch conversion product and preferably about two to three times this proportion of enzyme is used.

I find that this description is not sufficiently meaningful to someone skilled in the art so as to satisfy the statutory requirements. The instructions in the patent do not adequately describe the amount of enzyme preparation necessary in order to achieve the predicted results. The description in the patent gives a lower limit to the amount of enzyme preparation, and gives a "preferred" range of "about two to three times this proportion". No upper limit is given.

This description is clearly inadequate. For example, I find that a reader skilled in the art who might attempt to construct his own commercial process for the production of crystalline dextrose and wishes to know whether his process would be infringing is given no indication of how

much enzyme preparation Wallerstein used in his experiments or of how much the Wallerstein patent covers.

The third factor which the patent sets out is the time required for completion of the desired amount of hydrolysis. This requirement could be fulfilled by the patent setting out either the amount of hours necessary, or the yield of crystalline dextrose available in terms of a percentage of the amount of starch which was started with. To determine when the patented process was completed, one could then either look at his timepiece or test the solution to see if the desired yield has been achieved.

In this regard, the patent also fails. Column 3, Line 55, of the patent refers to "a starch-glucogenase activity sufficient to effect substantially complete hydrolysis of the starch substrate". While the upper limit of substantially complete hydrolysis may be taken as 100%, it is impossible to determine from the patent what is claimed as the lower limit of substantially complete hydrolysis".

The plaintiff might argue that in the claims the phrase "to convert a substantial proportion of the substance to dextrose", Column 6, Lines 50-51, may, by reference to the specification, be considered to have an upper limit of "about 90%" in Example 1; "95%" in Example 3; "about 97" in Example 4; and "84%" in Example 5. But reference to the specification yields no hint as to what is the lower limit below which there would be no infringement of the claims. Furthermore, the minimum value of dextrose in Column 6, Line 11, would prevent attaining the objects of the invention, namely, facilitation of crystallization, minimization of undersirable by-products and increasing yields of crystalline dextrose.

The patent does, of course, say that the process is completed in "not more than 72 hours", but as was pointed

out by Dr. Kooi at the trial, this is not a specific or clear indication to one skilled in the art. The description in the patent clearly gives an upper limit, but offers no indication of any lower limit. Without knowledge of this lower limit, the patent does not provide information sufficient for one skilled in the art to either copy the process described in the patent or know when his own process was infringing on the process claimed by the patent.

The specification, therefore, fails to adequately describe the time required for crystallization of the dextrose liquor, and likewise fails to disclose crystallization dextrose yields obtainable from the same. This makes it impossible to determine whether or not the objects of the invention are accomplished. The absence of full instructions as to time of crystallization and yield of dextrose crystals obtained prevents the reader who is skilled in the art from either judging the truth of the statement of objectives or of knowing whether he has performed the process in such a manner as to obtain the stated benefits.

The specification of the Wallerstein patent is not written in "full, clear, concise and exact terms", but in unreasonably loose, indefinite, inexact and functional, terms, which require the reader to guess at the meaning of such terms, or, alternatively, to stop and determine the meaning and scope by experiment.

It has for years been the policy of this country that in patents, "If the specifications do not describe the invention with reasonable certainty and precision, the patentee can claim nothing under his patent." *Carlton* v. *Brokee*, 84 U.S. 463 (1873).

Indefinite terms are used in the Wallerstein patent with the result that it is impossible for a reader to determine

what is and what is not an infringement. The terms relating to numerical values are stated in an indefinite manner, and the reader of the patent, even though skilled in the art, cannot tell what are the upper limits and lower limits of items covered by numerical expressions. The description in the specification is, therefore, indefinite and does not provide the basis for a valid patent.

With no upper limit and no lower limit as a guide, the reader is in the predicament of encountering a monopoly in the making of crystalline dextrose and yet being unable to determine what falls within and what falls without the monopoly. The indefinite character of the expressions used, if permitted, would benefit the patentee at the expense of the public, since disregarding the requirements of the statute would give the patentee a scope greater than he could obtain by accurate definition of his claimed monopoly, as required by the statute.

The public has a right to know the lower limit as well as the upper limit, and the patentee has the duty to inform the public as a part of the *quid pro quo* for the patent monopoly and to inform the public of the limits of the patent monopoly. Without this level of disclosure, the specification cannot tbe said to be a "full, clear, and concise statement".

In addition to lack of specificity referred to already, the patent fails to identify the enzyme preparation employed in the Examples 1 to 5 of the patent specification. Nowhere throughout the specification or claims is there any identifiable enzyme preparation disclosed.

While there is a statement in the specification that the starch-glucogenase enzymes useful in the invention may be obtained from various fungal sources, particularly the species of Aspergillus, such as Aspergillus oryzae, and

from ceretain bacterial species, for example, Clostridium acetobutylicum, there is no positive statement which indicates the specific microorganism used by the inventor.

In the course of pretrial discovery, the plaintiff admitted that its enzymes were all derived from Aspergillus oryzae. But, this information as to the origin of the enzyme was not made available to the public by the patent specification, and virtually is an admission by the plaintiff that the terms of the claims referring to "a microbiological enzyme preparation" are based solely on enzymes derived from Aspergillus oryzae and, hence, the claims are not only indefinite, but also plainly broader than the invention.

Finally, as further proof that the patent was loosely and inaccurately drafted, the defendant showed at the trial that the claims cover inoperative conditions. During the trial, the defendant introduced extensive evidence of experiments which were done under the direction of Dr. Kooi conforming to the teachings of the Wallerstein patent. It was Dr. Kooi's opinion, as one skilled in the art, that the description of the process provided in the patent was so broad and loosely worded that it covered what were shown to be inoperable conditions. The experiments which Dr. Kooi testified to were done after 1960 and after the suit was brought. However, these experiments conformed to the requirements set out in the patent and nevertheless failed to produce the results predicted by the patent. There was no testimony to the effect that these same non-conforming results would not have been obtained by one skilled in the art in 1950, when the patent was issued.

The fact that the patent is so broad as to cover inoperative conditions is alone a conclusive argument that it does not satisfy the specificity required by the statute. It does not "distinctly claim the subject matter which the applicant regards as his invention", but rather requires the reader to experiment in order to get the claimed results. Such a patent is invalid. See: *Standard Brands* v. *Yeast Corp.*, 308 U.S. 34, 38 (1933).

I would like to wholeheartedly commend the plaintiff's counsel for the excellent work done both on their written documents and during the trial. However, for the foregoing reasons, I find that there has been no infringement of the Wallerstein patent and judgment on the complaint will be entered for the defendant. I further find that the patent is invalid for failure to satisfy the requirements of 35 U.S.C. §112, and judgment on the counterclaim will likewise be entered for the defendant and the patent is hereby declared to be invalid. These remarks will stand in the records as my findings of fact and conclusions of law.

Enter:

/s/ James B. Parsons
United States District Judge

Date: April 28, 1967.